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                        THE UNITED STATES DISTRICT COURT
                   FOR THE NORTHERN DISTRICT OF CALIFORNIA
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                              SAN FRANCISCO DIVISION
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    STEVE ELLIS, TOM THEOBALD, JIM
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    DOAN, BILL RHODES, CENTER FOR
    FOOD SAFETY, BEYOND PESTICIDES,
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    SIERRA CLUB, and CENTER FOR
    ENVIRONMENTAL HEALTH,
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                                            Case No. 3:13-cv-01266-LB
                  Plaintiffs,
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                     v.
                                            FIRST AMENDED COMPLAINT FOR
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    STEVEN P. BRADBURY, DIRECTOR OF
                                            DECLARATORY AND INJUNCTIVE
    OFFICE OF PESTICIDE PROGRAMS,
                                            RELIEF
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    UNITED STATES ENVIRONMENTAL
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    PROTECTION AGENCY; and BOB
                                            Administrative Procedure Act Case
    PERCIASEPE, ACTING
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    ADMINISTRATOR AND DEPUTY
    ADMINISTRATOR, UNITED STATES
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    ENVIRONMENTAL PROTECTION
    AGENCY,
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                 Defendants.
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FIRST AMENDED COMPLAINT FOR DECLARATORY & INJUNCTIVE RELIEF

INTRODUCTION

- 1. This is a civil action for injunctive and declaratory relief. The original Complaint was dated Mar. 21, 2013. ECF No. 1. This First Amended Complaint is filed pursuant to a stipulation with the Defendants and approval by the Court dated May 17, 2013. ECF No. 17. Plaintiffs Steve Ellis, Tom Theobald, Jim Doan, Bill Rhodes, Center for Food Safety (CFS), Beyond Pesticides, Sierra Club, and Center for Environmental Health (CEH) (collectively Plaintiffs) challenge the actions of Defendants Steven P. Bradbury, Director of Office of Pesticide Programs of the United States Environmental Protection Agency (EPA), and Bob Perciasepe, Acting Administrator and Deputy Administrator of EPA (collectively EPA or Defendants) to allow the ongoing use of pesticide products containing the active ingredients clothianidin and thiamethoxam, in violation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et seq.; § 7(a)(2) of the Endangered Species Act (ESA), 16 U.S.C. § 1536(a)(2); and the Administrative Procedure Act (APA), 5 U.S.C. § 701 et seq.
- 2. Clothianidin and its parent compound, thiamethoxam, are two widely-used pesticides in a class of pesticides known as neonicotinoids, which have been shown to adversely impact the survival, growth, and health of honey bees and other pollinators vital to U.S. agriculture, and which have harmful effects on other animals, including threatened and endangered species. In a vast and extremely risky experiment, EPA has allowed over two million pounds of clothianidin and thiamethoxam to be used annually on more than 100 million acres and on dozens of different plant crops without adhering to existing procedural frameworks and with no adequate risk assessments in place.
- 3. In most instances, EPA has approved clothianidin and thiamethoxam product registrations, new uses, and use amendments without affording notice in the Federal Register and the opportunity for public comment, in violation of the FIFRA and the APA. Substantively, EPA has failed to modify its regulation of these pesticides in response to the many scientifically-sound studies and adverse effect reports illustrating the risks these neonicotinoid pesticides pose. EPA's regulatory approvals have been a major factor in excessive honey bee mortality and the

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decline of pollinator populations in the same time period. EPA's regulatory actions, resulting in the continued use of clothianidin and thiamethoxam, have also continued to place threatened and endangered species in jeopardy.

- 4. In addition to suffering chronic effects leading to excess mortality, which includes a phenomenon called Colony Collapse Disorder, hundreds of the nation's beekeepers and honey producers suffer from acute effects each spring, when neonicotinoid-treated corn, in particular, is planted in virtually every state. Tens of thousands of their bee colonies have been exposed to lethal levels of neonicotinoid-contaminated dust during corn planting season. Plaintiff beekeepers and honey producers have suffered, and will continue to suffer, devastating economic hardships unless Defendants take action, which they have refused to do despite repeated formal requests.
- 5. EPA is well aware of recent studies and reports illustrating the risks to honey bees, pollinators, and other sensitive species. In December 2010, Plaintiff Beyond Pesticides, along with other environmental groups, beekeepers, and honey producers, submitted a formal letter requesting that EPA issue a stop sale order of clothianidin products. EPA denied the request in February 2011.² In March 2012, Plaintiffs CFS and Beyond Pesticides, along with numerous other environmental groups, beekeepers, and honey producers, filed a legal petition (hereafter the Clothianidin Legal Petition or the Petition) asking EPA to initiate immediate suspension and cancellation of clothianidin products.³ EPA denied the suspension request in July 2012.⁴ Plaintiff CFS further submitted a comment letter regarding similar risks of

¹ Letter from Beyond Pesticides et al., to EPA (Dec. 8, 2010), available at http://www.epa.gov/opp00001/about/intheworks/clothianidin-petition2.pdf.

² Letter from Steven Bradbury, Director, Office of Pesticide Programs, EPA, to Steve Ellis *et al.* (Feb. 18, 2011), available at http://www.epa.gov/opp00001/about/intheworks/clothianidinresponse-letter.pdf.

³ CFS et al., Clothianidin Legal Petition (Mar. 21, 2012), available at http://www.centerforfoodsafety.org/wp-content/uploads/2012/10/CFS-Clothianidin-Petition-3-20-12.pdf.

⁴ Letter from Steven Bradbury, Director, Office of Pesticide Programs, EPA, to Peter T. Jenkins (July 17, 2012), available at http://www.epa.gov/opp00001/about/intheworks/epa-respns-toclothianidin-petition-17july12.pdf.

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thiamethoxam products and requesting suspension of the pesticide in October 2012.⁵ EPA also refused that suspension request.⁶

- 6. In addition to the Plaintiffs, hundreds of thousands of Americans endorsed an informal citizen petition between 2011 and 2012, urging Defendants to suspend clothianidin's registration. There is intense public interest in EPA's actions, due to the loss of honey bees and other beneficial insects; the resulting economic, food supply, and ecosystem damages; and the unnecessary persistent toxic pollution of America's private and public landscapes.
- 7. In allowing this scenario to unfold over the last thirteen years, EPA has violated the FIFRA, the ESA, and the APA. EPA has denied Plaintiffs and the public mandatory notice and public comment opportunities, severely damaged the interests of Plaintiffs, injured vital pollinators and threatened and endangered species, and caused unreasonable adverse environmental and economic impacts.

JURISDICTION AND VENUE

- 8. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1346 (United States as defendant), 28 U.S.C. §§ 2201-02 (declaratory relief), 5 U.S.C. § 702 (APA), 7 U.S.C. § 136n(a) (FIFRA), and 16 U.S.C. § 1540(e), (g) (ESA).
- 9. Jurisdiction is in the District Court under the ESA citizen suit provision, which allows "any person" to sue an agency "alleged to be in violation of any provision of [the ESA]" and provides that the "district courts shall have jurisdiction . . . to enforce any such provision or regulation" 16 U.S.C. § 1540(g)(1). Pursuant to the ESA, 16 U.S.C. § 1540(g)(2)(A), Plaintiffs CFS, Beyond Pesticides, Sierra Club, Steve Ellis, and Tom Theobald have provided Defendants with at least sixty days written notice of the their violations under the ESA and of Plaintiffs' intent to sue should Defendants fail to remedy such violations (hereafter the Sixty-Day Notice Letter). To date, Defendants have not remedied any of the violations of law set forth in

⁵ Letter from Plaintiffs to EPA (Oct. 16, 2012) (on file with Plaintiffs).

⁶ Letter from EPA to Plaintiffs (Feb. 27, 2013) (on file with Plaintiffs).

⁷ Sixty-Day Notice Letter from Plaintiffs Center for Food Safety *et al.* to Defendants and Ken Salazar, former Secretary of the Interior (Sept. 5, 2012) (on file with Plaintiffs).

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Plaintiffs' Sixty-Day Notice Letter.

10. Jurisdiction also lies in this Court under the FIFRA's judicial review provision, 7 U.S.C. § 136n(a), which provides:

District court review.

Except as otherwise provided in this Act, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by the district courts of the United States.

Each of the fourteen claims in this Complaint involve the refusal of the Defendants to cancel or suspend a registration or to change a classification not following a hearing, failure to conduct required ESA analysis and consultation, and other final actions of the Administrator not committed to his or her discretion; thus, jurisdiction lies properly in the District Court. 7 U.S.C. § 136n(a); 16 U.S.C. § 1540(g)(1). In particular, Defendants have: a) refused to cancel or suspend the conditionally registered uses of clothianidin and thiamethoxam despite clear evidence that the registrants for those uses have failed to comply with the conditions imposed by EPA; b) changed the classifications of numerous conditional registrations of thiamethoxam and clothianidin to <u>un</u>conditional registrations, as well as approved thiamethoxam and clothianidin products as unconditional registrations, despite the registrants' failures to comply with the conditions EPA imposed on them; c) taken final action, without a hearing, on Plaintiffs' Clothianidin Legal Petition in denying the request to declare an "imminent hazard" exists; d) failed to comply with the ESA, in approving all of the registered uses of these compounds, in converting registrations to the unconditional classification and in denying an "imminent hazard" exists; e) violated the FIFRA requirement to provide notices of clothianidin and thiamethoxam registrations and changed use applications in the Federal Register and allow public comment, as well as other notice requirements; f) approved inadequate labels under FIFRA and the ESA for clothianidin and thiamethoxam products; and g) taken other actions as alleged herein that caused unreasonable adverse environmental and economic impacts that are reviewable in the District Court.

one or more Plaintiffs reside in this district, and pursuant to 28 U.S.C. § 1391(e)(1)(b), because a

substantial part of the events or omissions giving rise to the claim occurred, or a substantial part

INTRADISTRICT ASSIGNMENT

the San Francisco or Oakland Divisions because one or more Plaintiffs reside in San Francisco.

PARTIES

(collectively Beekeeper and Honey Producer Plaintiffs) are being, and will be, adversely affected

by EPA's actions and inactions complained of herein. Beekeeper and Honey Producer Plaintiffs

Beekeeper and Honey Producer Plaintiffs are geographically and operationally representative of

Plaintiff Mr. Steve Ellis owns and operates Old Mill Honey Company, a

this essential agricultural sector, in which there are thousands of similarly-affected businesses

have suffered confirmed or unconfirmed clothianidin- and thiamethoxam-related kills to their

honey bees, both acute and chronic, as well as poor colony health and failure to thrive.

of property that is the subject of the action is situated, in this district.

An actual controversy exists between the parties within the meaning of 28 U.S.C.

Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e)(1)(c) because

Pursuant to Local Rule 3-2(c) and (d), assignment of this action is appropriate in

The interests of Plaintiffs Steve Ellis, Tom Theobald, Jim Doan, and Bill Rhodes

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and individuals.

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§ 2201 (declaratory judgment).

Beekeeper and Honey Producer Plaintiffs

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migratory beekeeping operation with 2,300 hives of bees during the summer honey-producing 21

season, and with several employees. The hives he manages for his business produce honey for

market over the summer months in Minnesota, and paid pollination services in the winter and

spring in California. Mr. Ellis has over thirty-five years of experience and has served as an

officer in beekeeper organizations for many years. He is the Secretary of the National Honey

Bee Advisory Board. His common beekeeping practices over the last decade include allowing

his bee colonies to forage, and often to do pollination, in the following types of crops and

habitats: almonds, corn, soybeans, sunflowers, edible beans, ornamental trees, forest trees,

FIRST AMENDED COMPLAINT FOR DECLARATORY & INJUNCTIVE RELIEF

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peaches, plums, residential and landscaped areas, golf courses, and lawns. Over the course of the last six to seven years, he has observed a new type of bee kill caused by pesticide poisoning in the early spring, especially, but not only, at corn seeding time, and early dandelion bloom. He has suffered major bee kills that were attributable to thiamethoxam and/or clothianidin. His fall and winter mortality have remained between 30–60% over this period. This level of losses is unsustainable. Mr. Ellis keeps bees in west central Minnesota where corn and soybeans are increasingly the dominant crops. It is not practically feasible to locate his bees away from these crops during the summer growing season.

- 17. Plaintiff Mr. Tom Theobald is a commercial beekeeper and owner of the Niwot Honey Farm in Niwot, Colorado. He has conducted his beekeeping business for thirty-eight years. He was the President of the Boulder County Beekeepers Association for thirty years. Mr. Theobald served two terms as Vice-President of the Colorado Beekeepers' Association and was the last County Bee Inspector in Colorado. He is losing 40–60% of his colonies each year and in 2011 and again in 2012 had his smallest honey crops in thirty-seven years. His common beekeeping practices over the last decade include allowing his bee colonies to forage in the following types of crops and habitats: corn, sunflowers, apples and other fruit trees, ornamental trees, residential gardens, and various turf and/or lawn applications. He has observed, based on his long personal and government experience with the impacts of various pesticides on bees as well as through his own research, that a primary cause of his recent and continuing losses is the uncontrolled use of neonicotinoid pesticides (including clothianidin and thiamethoxam) over vast acres of agricultural land near his business, as well as on untold acres of nearby urban and suburban land in Boulder County.
- 18. Plaintiff Mr. Jim Doan has run Doan Family Farms based in Hamlin, New York, with his wife, son and several hired men. He has kept honey bees for forty-five years. In 2006 Mr. Doan ran as many as 5,300 hives in New York and Florida; his bees pollinate a vast portion of New York's apple crop each year. His common beekeeping practices over the last decade include allowing his bee colonies to forage, and often to do pollination, in the following types of crops and habitats: corn, soybeans, cucumbers, pumpkins, squash, melon, citrus, ornamental

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trees, apples, other fruit trees, residential and landscaped areas, wheat, cabbage, berries, peas, and green beans. Since 2006, he has been unable to keep from losing more than 50% of his hives each year to symptoms that, based on his experience, are caused by both acute and chronic exposure to the new neonicotinoid pesticides. In the spring and summer of 2012, Mr. Doan suffered a devastating bee kill caused by clothianidin, which very clearly came from contaminated dust and other exposure routes related to the several cornfields around his bee colonies. He feared that if he continued to suffer such losses to his business, without monetary support, it would be doomed to disappear. His bees could not be replaced as fast as they were dying.

- 19. In late May 2013, in response to another massive bee kill, Mr. Doan was compelled to sell Doan Family Farms and he has had to reduce his many-decades old beekeeping business. While he remains a beekeeper, the financial and personal strains of repeated massive neonicotinoid bee kills in addition to the other pressures of the business may be too much for him to continue.
- 20. Plaintiff Mr. Bill Rhodes owns Bill Rhodes Honey Company, the largest commercial honey producer in Florida, based in Umatilla. A beekeeper for forty-one years, his company employs about fifteen people. His common beekeeping practices over the last decade include allowing his colonies to forage in the following types of crops and habitats: corn, soybeans, sunflowers, and residential areas with lawns, gardens, and other landscaping. Mr. Rhodes produces several premium honey varieties, both in Florida and South Dakota, and his company also ships bees to Georgia and other states. He seeks to maintain about 9,000 hives, but the impacts of pesticides, including thiamethoxam and clothianidin, make keeping that level very difficult. Mr. Rhodes started seeing symptoms of Colony Collapse Disorder around 2004 and 2005, and again in 2007 and 2008. In the latter year he lost 7,200 of 9,000 hives. Major losses have continued, far exceeding normal loss rates during the three earlier decades of his operations. Mr. Rhodes has seen other beekeepers driven out of the business from major losses, and has a high level of concern that his own livelihood based on premium honey production is threatened.

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- 21. The use of systemic pesticides such as thiamethoxam and clothianidin is not posted with signs nor is any other notice provided to beekeepers about their use as a matter of common practice. Based on the Beekeeper and Honey Producer Plaintiffs' years of experience and their knowledge of the use of neonicotinoids on a broad range of U.S. crops and habitats, the Beekeeper and Honey Producer Plaintiffs are reasonably certain that their bees were frequently exposed to these systemic insecticides in many of the crops and habitats their bees visited, as well as within their own hives via dust, pollen, and other exposure routes. The Beekeeper and Honey Producer Plaintiffs are also concerned that in the future their bees will be exposed to, and further weakened or killed by, thiamethoxam and clothianidin used in the crops and habitats their bees visit, other crops and habitats, as well as cumulative soil residues of thiamethoxam and clothianidin in those habitats.
- 22. Each of the Beekeeper and Honey Producer Plaintiffs is injured by EPA's actions and inactions complained of herein. EPA's failure to provide Beekeeper and Honey Producer Plaintiffs with the FIFRA-mandated notices of application for clothianidin and thiamethoxam registration and changed uses in the Federal Register, and its failure to provide mandatory public comment periods, denied Plaintiffs the ability to submit information to the EPA that may have convinced the agency not to issue those registrations or use amendments. For Beekeeper and Honey Producer Plaintiffs, the monetary damages to their businesses are significant, including the costs of replacing killed and weakened bees; contaminated beeswax, comb, and hives; reduced honey production and lost profits; increased labor, equipment, and supply expenditures; and costs and lost profits from the inability to perform contracted pollination services. Their losses are not insured or insurable. On a personal level, they have suffered from increased workload to address bee kills and poor bee health, and personal stress and anxiety from seeing the valuable animals in their care die, as well as being compelled to pursue enforcement actions with government agencies about their farmer neighbors, and other damages. The relief sought in this case will provide redress for their ongoing harms and aid in preventing additional future damages from clothianidin and thiamethoxam, which are expected to worsen in the future absent change.

Public Interest Group Plaintiffs

- 23. The interests of CFS, Beyond Pesticides, Sierra Club, and CEH (collectively Public Interest Group Plaintiffs) and their members are being, and will be, adversely affected by EPA's actions and inactions complained of herein. EPA's continued registrations of clothianidin and thiamethoxam products and failure to take regulatory actions to suspend or cancel such product registrations harm the interests of Public Interest Group Plaintiffs and Public Interest Group Plaintiffs' members. EPA's actions and inactions have, and will continue to have, an adverse effect on Public Interest Group Plaintiffs' missions and their members' conservation, environmental, recreational, aesthetic, and economic interests.
- 24. Plaintiff CFS brings this action on behalf of itself and its members. CFS and its members are being, and will be, adversely affected by EPA's actions and inactions complained of herein. CFS is a Washington, D.C.-based, public interest, nonprofit membership organization that has offices in San Francisco, CA; Portland, OR; and Washington, D.C.
- 25. Since CFS's founding in 1997, it has sought to ameliorate the adverse impacts of industrial farming and food production systems on human health, animal welfare, and the environment. CFS has over 280,000 members nationwide. CFS seeks to protect human health and the environment by advocating for thorough, science-based safety testing of new agricultural products prior to any marketing and cultivation of crops in a manner that minimizes negative impacts such as increased use of pesticides and evolution of resistant pests and weeds. A foundational part of CFS's mission is to further the public's fundamental right to know what is in their food and food production methods.
- 26. Plaintiff Beyond Pesticides brings this action on behalf of itself and its members. Beyond Pesticides and its members are being, and will be, adversely affected by EPA's actions and inactions complained of herein. Based in Washington, D.C., Beyond Pesticides is a national nonprofit corporation that promotes safe air, water, land, and food, and works to protect public health and the environment by encouraging a transition away from the use of toxic pesticides.

- 27. With Beyond Pesticides's resources made available to the public on a national scale, Beyond Pesticides contributes to a significant reduction in unnecessary pesticide use, thus improving protection of public health and the environment.
- 28. Plaintiff Sierra Club brings this action on behalf of itself and its members. Sierra Club and its members are being, and will be, adversely affected by EPA's actions and inactions complained of herein. The Sierra Club is a national nonprofit organization of approximately 600,000 members dedicated to exploring, enjoying, and protecting the wild places of the earth; to practicing and promoting the responsible use of the earth's ecosystems and resources; to educating and enlisting humanity to protect and restore the quality of the natural and human environment; and to using all lawful means to carry out these objectives. The Sierra Club is a California nonprofit corporation headquartered in San Francisco, CA.
- 29. The Sierra Club's concerns encompass endangered species, habitat protection, pollution, and industrial agriculture, all of which are involved in this case. The loss of bees and other beneficial insects, and the threats to native ecosystems and wildlife posed by neonicotinoid insecticides, harm the interests of the Sierra Club and its members.
- 30. Plaintiff CEH is a tax-exempt, nonprofit corporation with offices in Oakland, California; and New York, New York. Founded in 1996, CEH is a nonprofit organization dedicated to protecting the public from environmental and public health hazards, including harmful pesticides. CEH achieves its mission by working with communities, consumers, workers, government, and the private sector to demand and support business and agricultural practices that are safe for public health and the environment.
- 31. As part of its mission, CEH and its staff have long been involved in efforts to combat the negative human health and environmental effects of pesticides and other harmful contaminants in our food system. For example, CEH is a member of Californians for Pesticide Reform, an organization whose mission is to protect public health, improve environmental quality, and expand a sustainable and just agriculture system by seeking to change state and local pesticide policies and practices. CEH's Research Director, Caroline Cox, serves on the California Department of Pesticide Regulation's Pest Management Advisory Committee and is a

member of the Board of Beyond Pesticides. When necessary, CEH also engages in public interest litigation to address the food safety concerns raised by the current regulatory framework and the negative impacts of unsafe products. The interests of CEH and its members in reducing the harmful impacts stemming from pesticide use are being, and will be, adversely affected by EPA's ongoing registrations of clothianidin and thiamethoxam products.

- 32. Public Interest Group Plaintiffs and their members have a vital interest in the survival and health of honey bees and other plant pollinators to ensure a nutritious and safe food supply and healthy natural ecosystems and gardens. Each of the Public Interest Group Plaintiffs has a strong interest in the conservation of the vast numbers of native ESA-listed species that are potentially impacted, directly and indirectly, by clothianidin and thiamethoxam. Several of the Public Interest Group Plaintiffs and their members have personally visited the ranges of directly impacted ESA-listed invertebrates, including, but not limited to, listed plant pollinators, as well as other indirectly impacted ESA-listed species, including, but not limited to, rangeland and other birds. They enjoy utilizing these species for recreational, aesthetic, and other uses, and intend to continue to visit those habitats and enjoy those species and the ecosystem services they provide.
- 33. EPA's failure to provide Public Interest Group Plaintiffs with the FIFRA-mandated notices of applications for the clothianidin and thiamethoxam registration and changed uses in the Federal Register, and its failure to provide public comment periods, denied the Public Interest Group Plaintiffs the ability to submit information to EPA that may have convinced the agency not to issue those registrations or change amendments. Defendants' failure to adequately regulate clothianidin and thiamethoxam under FIFRA and the ESA, and failure to provide adequate label warnings on these pesticides, resulting in the ongoing collapse of populations of honey bees and other beneficial insects and the continued harm to threatened and endangered species, further injure Public Interest Group Plaintiffs' organizational interests as well as their members' aesthetic, recreational, and economic interests. The relief sought in this case will provide redress for the ongoing harm to Public Interest Group Plaintiffs and their members.

Defendants

- 34. Defendant Steven P. Bradbury is the Director of the Office of Pesticide Programs of EPA, and is being sued in his official capacity.
- 35. Defendant Bob Perciasepe is the Acting Administrator and Deputy Administrator of EPA, and is being sued in his official capacity.
- 36. Defendants Bradbury and Perciasepe are collectively referred to as EPA or Defendants.

STATUTORY BACKGROUND

Federal Insecticide, Fungicide, and Rodenticide Act

37. Under the FIFRA, EPA licenses the sale, distribution, and use of pesticides through the process of registration. 7 U.S.C. § 136a. The Administrator is required to provide public notice and comment opportunities under 7 U.S.C. § 136a(c)(4):

Notice of application.

The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.

38. EPA's FIFRA-implementing regulations also impose several procedural requirements, including, but not limited to, requiring publication of two classes of notices in the Federal Register. Under 40 C.F.R. § 152.102:

The Agency will issue in the Federal Register a <u>notice of receipt of each application for registration</u> of a product that contains a new active ingredient or that proposes a new use. After registration of the product, the Agency will issue in the Federal Register a <u>notice of issuance</u>. The notice of issuance will describe the new chemical or new use, summarize the Agency's regulatory conclusions, list missing data and the conditions for their submission, and respond to comments received on the notice of application.

Id. (emphases added).

39. The FIFRA authorizes Defendants to register a pesticide product without any conditions (unconditional registration) if Defendants determine that the product "will perform its

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intended function without unreasonable adverse effects on the environment," and that "when used in accordance with widespread and commonly recognized practice" the pesticide "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C)-(D).

- 40. The FIFRA authorizes Defendants to register a pesticide product with conditions (conditional registration) if Defendants determine that the pesticide or proposed new use is so new that insufficient data exists to support unconditional registration under 7 U.S.C. § 136a(c)(5), provided that the registrants meet Defendants' conditions, and conduct and supply studies to fill the missing data gaps within a set timeframe. 7 U.S.C. § 136a(c)(7)(C). A conditional registration is authorized under three circumstances: 1) EPA may conditionally register a pesticide if "the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and [] approving the registration . . . would not significantly increase the risk of any unreasonable adverse effect on the environment," 7 U.S.C. § 136a(c)(7)(A); 2) EPA may conditionally amend a pesticide's registration "to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment," 7 U.S.C. § 136a(c)(7)(B); and 3) EPA may conditionally register a pesticide "containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data" but "only if [EPA] determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest," 7 U.S.C. § 136a(7)(C) (emphasis added).
- 41. Under the FIFRA, a conditional registration may only last for a period "reasonably sufficient" to generate the outstanding data necessary for unconditional registration. 7 U.S.C. § 136a(c)(7)(C).
- 42. EPA has the authority to cancel a pesticide registration whenever "a pesticide or its labeling . . . does not comply with the provisions of [the FIFRA] or, when used in accordance

with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment." 7 U.S.C. § 136d(b).

- 43. EPA may immediately suspend a pesticide registration to prevent an "imminent hazard." 7 U.S.C. § 136d(c). The phrase "imminent hazard," as defined in the FIFRA, means a situation "when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered" under the ESA. 7 U.S.C. § 136(l).
- 44. If a registrant has failed to fulfill any condition imposed on the registration, the Administrator "shall" initiate cancellation proceedings. 7 U.S.C. § 136d(e)(1). While cancellation is pending, EPA may suspend the registration of the pesticide or new use immediately if an "imminent hazard" exists, that is, if "continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary [of the Interior] pursuant to the Endangered Species Act of 1973." 7 U.S.C. §§ 136d(c), 136(l).
- 45. The culmination of the registration process is EPA's approval of a label for the pesticide, including use directions and appropriate warnings on safety and environmental risks. It is a violation of the FIFRA for any person to sell or distribute a "misbranded" pesticide. 7 U.S.C. § 136j(a)(1)(E). A pesticide is misbranded if the "labeling accompanying it does not contain directions for use which . . . if complied with . . . are adequate to protect health and the environment." 7 U.S.C. § 136(q)(1)(F).
- 46. The FIFRA registrations for clothianidin and thiamethoxam products amount to licenses that establish the terms and conditions under which the products may be lawfully sold, distributed, or used. EPA retains the ongoing authority to modify the terms and conditions of these licenses as needed; thus, each pesticide registration constitutes an ongoing agency action. *See* 7 U.S.C. §§ 136d(c), 136(l).

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47. The legal burden of showing that any pesticide and any approved uses thereof meet the FIFRA criteria to be eligible for continued registration rests with the products' proponents. See 40 C.F.R. § 154.5.

Endangered Species Act

- 48. The ESA requires EPA, in consultation with U.S. Fish and Wildlife Service (FWS), to ensure that any action authorized by the agency is not likely to jeopardize the continued existence of any threatened or endangered species, or result in the destruction or adverse modification of the critical habitat of such species. 16 U.S.C. § 1536(a)(2). For each federal action, EPA must request information from FWS indicating whether any listed or proposed species may be present in the area of the agency action. 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12. If listed or proposed species may be present, EPA must prepare a "biological assessment" to determine whether the listed species may be affected by the proposed action. 16 U.S.C. § 1536(c)(1); 50 C.F.R. § 402.12.
- 49. If EPA determines that its proposed action may affect any listed species or critical habitat, the agency must engage in formal consultation with FWS. Effects determinations are based on the direct, indirect, and cumulative effects of the action when added to the environmental baseline and other interrelated and interdependent actions. 50 C.F.R. § 402.02. An agency is required to review its actions "at the earliest possible time" to determine whether the action may affect listed species or critical habitat. 50 C.F.R. § 402.14(a). Because EPA retains ongoing discretionary authority to modify the terms and conditions of its approvals, the agency's continuing authority over pesticide registrations constitutes ongoing agency action and it has a continuing obligation to follow the requirements of the ESA.
- 50. To complete formal consultation, FWS must provide EPA with a "biological opinion" explaining how the proposed action will affect the listed species or habitat. 16 U.S.C. § 1536(b). If FWS concludes the proposed action will jeopardize the continued existence of a listed species, the biological opinion must outline "reasonable and prudent alternatives." 16 U.S.C. § 1536(b)(3)(A). If the biological opinion concludes the action is not likely to jeopardize the continued existence of a listed species, and will not result in the destruction or

adverse modification of critical habitat, FWS must provide an incidental "take" statement specifying the impact of such incidental taking on the listed species and any "reasonable and prudent measures" that FWS considers necessary or appropriate to minimize such impact, and also setting forth the "terms and conditions" that must be complied with by EPA to implement those measures. 16 U.S.C. § 1536(b)(4).

- 51. "Take" is defined broadly to include actions that "harass, harm, pursue, hunt, shoot, wound, [or] kill" a protected species, either through direct action or by degrading its habitat. 16 U.S.C. § 1532(19); 50 C.F.R. § 17.3. In furtherance of Congress's goal to conserve species, the ESA generally prohibits the "take" of any species listed as endangered, a prohibition FWS has extended by regulation to threatened species. 16 U.S.C. § 1538(a)(1)(B); *see also* 16 U.S.C. § 1533(d); 50 C.F.R. § 17.31. However, take that complies with the terms and conditions specified in a biological opinion is not prohibited. 16 U.S.C. § 1536(o)(2).
- 52. During consultation with FWS, EPA is prohibited from making any irreversible or irretrievable commitment of resources with respect to the agency action which may foreclose the formulation or implementation of any reasonable and prudent alternative measures. 16 U.S.C. § 1536(d).
- 53. Section 7 of the ESA also requires EPA, in consultation with and with the assistance of FWS, to utilize its authority in furtherance of the purposes of the ESA by carrying out programs for the conservation of endangered and threatened species. 16 U.S.C. § 1536(a)(1). *Administrative Procedure Act*
- 54. The APA provides for judicial review of final agency actions. "Agency action" is defined to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. § 551(13). The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.
- 55. Under the APA, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions" that it finds to be "arbitrary, capricious, an abuse of discretion,

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or otherwise not in accordance with the law" or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (D).

56. Further, under the APA, a reviewing court has the authority to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

STATEMENT OF FACTS

Honey Bee Impact Facts

- 57. Clothianidin and thiamethoxam are systemic insecticides that are formulated and sold as a large number of branded products aimed at a variety of agricultural, landscaping, and residential use markets. They are taken up by a plant's vascular system as it grows and are expressed through its tissues, including flowers, pollen, and nectar. They share a common mode of action that damages the central nervous system of honey bees. When bees forage on pollen or nectar from treated crops and other plants, or are otherwise exposed to even extremely small levels of these compounds, paralysis and death can result. Over the past decade, the proliferating use of the neonicotinoid class of pesticides has coincided with mass die-offs of honey bee populations in the phenomenon known as Colony Collapse Disorder, documented as early as 2003–2004 in the United States, with the first reported case findings in 2006.
- 58. Clothianidin is a transformation product of thiamethoxam. In honey bees, thiamethoxam is metabolized into clothianidin. In short, the two are closely related with comparable applications, toxicity, and effects.
- 59. Clothianidin and thiamethoxam affect bee behavior and cognition in ways that compromise the overall health of colonies, often causing bee colonies to collapse. Honey bees are social insects that rely heavily on memory, cognition, and communication to coordinate activities essential for their survival. Chronic ingestion of neonicotinoids damages foraging behavior, overall mobility, and the communication by which they coordinate their activities. Neonicotinoid pesticides can also have several other indirect effects on honey bees, such as causing premature shifts in hive roles. They can impair honey bees' medium-term olfactory memory and associative learning abilities, which foraging honey bees rely on, inter alia, to find their way back to the hive.

- 60. Neonicotinoid pesticides such as clothianidin and thiamethoxam persist in a toxic state in the environment for several years, increasing the risk of cumulative toxic loading effects, especially after repeat applications at the same location. No label warnings or use directions are capable of mitigating these impacts and those warnings and directions that do exist are almost never enforced. Farmers and other users are known to ignore them in many cases, yet enforcement cases by EPA and its cooperating state agencies are exceedingly rare.
- thiamethoxam are spread widely throughout hundreds of millions of acres of both agricultural and neighboring lands. The neighboring lands are where these toxic compounds are not intended to be and often are lands not owned by the farmers applying the compounds. These lands adjacent to agricultural fields in many cases are prime remaining bee and native insect habitats. Due to the long persistence of these compounds and the uncontrollable drifting and blowing of contaminated dust and soil, bees and other insects are victims of multiple exposure pathways that EPA failed to assess when the agency approved the pesticides—and still has failed to assess. Key among these exposure pathways are residues in pollen and nectar, dust from treated seeds and soils, planter exhaust, untreated but contaminated non-crop plants adjacent to treated fields, contaminated puddles in fields and adjacent surface water, guttation droplets on both treated and untreated but contaminated plants, and residues from foliar uses.
- 62. EPA's own scientists have regularly described severe impacts of these insecticides in their internal risk assessments. Recent studies, including those by the U.S. Department of Agriculture (USDA)'s lead bee scientists, also confirm that neonicotinoids interact with common bee pathogens and parasites, making them more vulnerable to the deadly effects of both, leading to further colony collapse. Numerous recent peer-reviewed studies and other evidence of both acute and sub-lethal harm to bees from a variety of exposure pathways across diverse agricultural landscapes support the need to suspend the uses of clothianidin and thiamethoxam. EPA has failed to take this new science into account in: a) deciding whether an "imminent hazard" exists requiring suspension of these pesticides; b) determining the adequacy

of the pesticide products' labeling under FIFRA; and c) initiating and completing consultation regarding potential impacts on federally-listed threatened and endangered species under the ESA.

- 63. Other nations, including Austria, Italy, France, Germany, Slovenia, and Sweden, and recently the European Union as a whole, have recognized the imminent harm of seed treatment and other uses of clothianidin and thiamethoxam and suspended or restricted those uses. In past cases, these actions restricting or suspending the uses of clothianidin and thiamethoxam have generally allowed honey bee colonies to thrive.
- 64. EPA has maintained the active registrations of clothianidin and thiamethoxam products despite known risks and data gaps. The European Food Safety Authority has issued authoritative reports that confirm that clothianidin and thiamethoxam products present acute risks to honey bee survival—risks that the European Food Safety Authority characterized as having been underestimated and inadequately researched by national pesticide regulators. A <a href="https://district.org/high.gov/high
- 65. EPA has suggested non-mandatory best management practices (BMPs) that it might promote to reduce the unreasonable adverse environmental effects of thiamethoxam and clothianidin. However, EPA lacks authority to mandate adherence to all of the needed technological fixes and BMPs. EPA officials have publicly stated they lack comprehensive enforcement power under the FIFRA to prevent farmers from killing bees and other pollinators via the contaminated dust pathway associated with planting treated seeds. Even if they had such authority, the time lag for the hundreds of thousands of users of clothianidin and thiamethoxam products to be able to comply is such that the unreasonable adverse environmental effects would continue for many years unless use of these products is suspended in the interim. EPA's

suggested non-mandatory BMPs are inadequate for purpose of compliance with the FIFRA and the ESA.

- 66. As a result, clothianidin- and thiamethoxam-treated seeds will continue to be planted across hundreds of millions of acres in 2013 and beyond. To date, EPA has provided no formal direction or label changes to farmers on how to minimize non-target effects, how and where to clean out crop planters, or what steps to take to avoid effects to nearby honey bees or insect-pollinated plants. Consequently, Defendants have allowed the imminent hazard to continue to occur, in particular as corn and other crops are planted in the spring season. Since the original filing of this case in March 2013, at least two of the Beekeeper and Honey Producer Plaintiffs, and numerous other beekeepers across the nation, have experienced increased mortality of their managed beehives due to this ongoing hazard, as corn and other crops are planted in the months of April and May. One Beekeeper and Honey Producer Plaintiff, Jim Doan, was driven out of his farm business in May 2013 because of increased mortality of his bees from exposure to these neonicotinoid pesticides.
- 67. The winter of 2012-2013 was the worst year in recent years for bee mortality, with official USDA estimates exceeding 30% bee loss, but with several of the Beekeeper and Honey Producer Plaintiffs and numerous other beekeepers across the nation experiencing much worse, with 40%, 60%, and up to 100% bee losses.
- California, which requires millions of bee colonies, almost failed in January through March of 2013 due to lack of viable colonies. Experts have identified systemic neonicotinoid insecticide use is a major contributing factor to the shortage of viable pollinators and honey bee populations, in combination with other factors. Experts have identified the potential for foreseeable "domino effects" of cascading inadequate crop pollination due to shortages of viable pollinators. This could rapidly evolve into devastating, perhaps irreversible, losses to farmers, consumers, and the economy as a whole, since all rely on domestically-produced bee-pollinated food and fiber crops. The future of commercial beekeeping is in jeopardy. Economic losses from the collapse of U.S. bee colonies used in agriculture would measure in the several tens of billions of dollars. The

ecological, agricultural, landscaping, and horticultural impacts of lost managed and wild pollinators would be devastating and perhaps irreparable.

- 69. In recent months, EPA officials have made key public admissions at public meetings, in media statements, in EPA documents, and at other venues. They have admitted that a) EPA's enforcement guidance for neonicotinoid use is inadequate; b) EPA's bee kill incident reporting system is inadequate; and that c) the labels on neonicotinoid products are inadequate to mitigate adverse environmental effects, including the risk of seed dust-mediated mortality to honey bees and other beneficial insects in or near corn fields. EPA officials have publicly recognized the current corn planting machinery poses significant risks and needs changing, while also recognizing that such changes will likely take many years and stating that EPA lacks authority to mandate machinery changes. Despite these and other key admissions about the current crisis in bee health, EPA has refused to exercise its regulatory power to address the one factor it could address immediately—the major contribution of clothianidin and thiamethoxam to bee declines.
- 70. The efficacy of clothianidin and thiamethoxam seed treatments and other uses are highly debated. Despite claims of benefits by the registrants and in public statements by EPA officials, many recent studies indicate that they provide no yield benefit in many cases and their prophylactic use exacts severe costs to beneficial insects, biological control agents, and ecosystems. In sum, their costs to the nation as a whole exceed their benefits.

Non-Honey Bee Impact Facts

71. Besides honey bees, there are thousands of other U.S. native bee and other insect species that EPA has a duty to conserve, including, but not limited to, the rusty patched bumble bee, Franklin's bumble bee, yellow-banded bumble bee, and Western bumble bee, as well as non-bee insects such as butterflies, ladybugs and lacewings, dragonflies, and hoverflies. Several of these species are facing severe declines comparable to, or worse than, those faced by honey bees. Clothianidin and thiamethoxam are documented to be highly toxic to other bee species like the common Eastern bumble bee, alfalfa leafcutter bee, and blue orchard bee, all of which are valuable plant pollinators. There are numerous other beneficial insects and other invertebrates

that are severely impacted by use of clothianidin and thiamethoxam. Broad recognition exists, including by EPA, that there is insufficient data to assess the impacts of clothianidin and thiamethoxam use on the behavior, reproduction, and survival of these vital pollinators and insect species.

- 72. EPA has never done a thorough effects analysis of the numerous thiamethoxam or clothianidin uses it has approved for any federally-listed threatened and endangered species under the ESA, and EPA similarly has failed to assess potential adverse modification of designated critical habitat. It also has failed to consult with FWS as required under the ESA.
- 73. More than fifteen threatened or endangered insects, including, but not limited to, plant pollinators, ranging from beetles to butterflies to grasshoppers and other taxa, are potentially directly affected by the use of clothianidin and thiamethoxam products. By way of illustration, these species include, but are not limited to (followed by their listing dates; the vast majority were listed prior to the dates of EPA's actions at issue in this First Amended Complaint):

American burying beetle (<i>Nicrophorus americanus</i>)	07/13/1989
Behren's fritillary (Speyeria zerene behrensii)	12/05/1997
Callippe silverspot (Speyeria callippe callippe)	12/05/1997
Delhi Sands flower-loving fly (Rhaphiomidas	09/23/1993
terminatus abdominalis)	
Fender's blue (Icaricia icarioides fenderi)	01/25/2000
Hine's emerald dragonfly (Somatochlora hineana)	01/26/1995
Karner blue (Plebejus melissa samuelis)	12/14/1992
Kern primrose sphinx moth (Euproserpinus euterpe)	04/08/1980
Lange's metalmark (Apodemia mormo langei)	06/01/1976
Mitchell's satyr butterfly (Neonympha mitchellii	05/20/1992
mitchelli)	
Myrtle's silverspot (Speyeria zerene myrtleae)	06/22/1992
Northeastern beach tiger beetle (Cicindela	08/07/1990
dorsalis dorsalis)	
Ohlone tiger beetle (Cicindela ohlone)	10/03/2001
Quino checkerspot butterfly (Euphydryas editha	01/16/1997
quino)	
Salt Creek tiger beetle (Cicindela nevadica	10/06/2005
lincolniana)	
San Bruno elfin (Callophrys mossii bayensis)	06/01/1976
Schaus swallowtail (Papilio aristodemus	listed as threatened 4/22/1975;
ponceanus)	as endangered 8/31/1984

Zayante band-winged grasshopper (*Trimerotropis infantilis*)

01/24/1997

More insect species are regularly listed and numerous "Candidate" species, including native bees, await further action.

- 74. Harmful direct, indirect, and cumulative effects on many other non-insect ESA-listed species, including, but not limited to, birds, crustaceans, mollusks, fish, mammals, reptiles, and amphibians, are also foreseeable due to the known effects of clothianidin and thiamethoxam. Listed species may be affected by direct consumption of clothianidin- and thiamethoxam-treated seeds and plant parts, as well as by food chain and ecosystem collapses associated with the vast mortality caused by these pesticides to aquatic and terrestrial invertebrates. EPA has not made the required "effects" determinations or consulted with FWS for any listed species or their critical habitats.
- 75. In its initial conditional registration of clothianidin, EPA recognized that compliance with the ESA is necessary:

Clothianidin is expected to present acute and/or chronic toxicity risk to endangered/threatened birds and mammals via possible ingestion of treated corn and canola seeds. Endangered/threatened non-target insects may be impacted via residue laden pollen and nectar. The potential use sites cover the entire U.S. because corn is grown in almost all U.S. states.⁸

EPA has made the same admissions in its thiamethoxam documentation.⁹

76. For at least one neonicotinoid insecticide, FWS scientists are on record stating "EPA is ignoring their duties with respect to consulting with FWS." ¹⁰ This is in fact true for all thiamethoxam and clothianidin product approvals subject to this Action. According to EPA documents, there are hundreds of federally-listed threatened and endangered species occurrences

⁸ EPA, Pesticide Fact Sheet: Clothianidin, Conditional Registration 16 (May 30, 2003), *available at* http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-044309_30-May-03.pdf.

⁹ See, e.g., EPA, Thiamethoxam Summary Document Registration Review: Initial Docket 5 (Dec. 2011), available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0581-0002.

¹⁰ E-mail from Ken Dickerson, Environmental Contaminants Biologist, FWS, to Nancy Golden, FWS, regarding initiating informal consultation on rodenticide new uses (Jan. 3, 2012) (on file with Plaintiffs).

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in states where clothianidin and thiamethoxam are used in which direct or indirect effects are foreseeable, but EPA has disregarded those effects determinations with respect to the ESA § 7 consultation requirements.

77. In March 2013, the American Bird Conservancy of Washington, D.C., released a

highly relevant scientific report, The Impact of the Nation's Most Widely Used Insecticides on Birds. 11 It was researched and written by a recognized independent avian toxicologist, Pierre Mineau, Ph.D. In the report, Dr. Mineau examines the key EPA risk assessment documents and finds numerous critical errors and failures related to risks to birds in the agency's approvals of clothianidin and thiamethoxam products. The report shows high direct and indirect mortality risks to a broad suite of birds, as well as to aquatic invertebrates and to ecosystems generally. It finds that the observed acute threats to aquatic invertebrates from water contamination by EPAapproved neonicotinoids "may be totally unprecedented in the history of pesticide registration." Id. at 57. It also states: "Simply put, EPA has not been heeding the warnings of its own toxicologists." Id. at 65. In the report, Dr. Mineau examines the EPA-approved product labels and finds them inadequate to address the risks to birds. The report states: "regulators are clearly mistaken in believing that exposure to [neonicotinoid] treated seed can be minimized by label statements or adherence to good agricultural practices." Id. at 27. The report describes EPA's analysis of avian risks as "scientifically unsound," arbitrary, and capricious. It urges, inter alia, the agency to suspend use of these products until the risks are resolved and to ban seed treatments altogether.

78. Recently published water quality studies have indicated that neonicotinoid insecticide pollution occurring in surface waters has a strong negative effect on aquatic invertebrate life, with potentially far-reaching consequences for the food chain and ecosystem

¹¹ Dr. Pierre Mineau and Cynthia Palmer, Am. Bird Conservancy, *The Impact of the Nation's Most Widely Used Insecticides on Birds* (Mar. 2013), *available at* http://www.abcbirds.org/abcprograms/policy/toxins/Neonic_FINAL.pdf.

functions. EPA's approvals of the numerous thiamethoxam and clothianidin products failed to consider these threats.

Procedural Background Facts

- 79. Since 2000 and 2003, respectively, EPA has registered approximately more than 100 total thiamethoxam and clothianidin insecticide uses and products under FIFRA. *See* Appendices A and B. On information and belief, these are as indicated in Appendix A Clothianidin (thirty-five products) and B Thiamethoxam (sixty-eight products), which are incorporated into this Complaint by this reference. Other registrations are believed to exist; however, due to EPA's failure to publish required notices in the Federal Register, there is a lack of accurate and clear public records. On information and belief, for the vast majority of clothianidin and thiamethoxam registrations and changed use approvals, EPA did not, as required under the FIFRA, 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102, announce a "notice of receipt of application" or a "notice of issuance" in the Federal Register or in any other public order or hearing.
- 80. Additionally, on information and belief, for each of the thiamethoxam and clothianidin insecticide uses and products, EPA failed this requirement under the FIFRA: "within 30 days after the Administrator registers a pesticide under this Act the Administrator shall make available to the public the data called for in the registration statement." 7 C.F.R. § 136a(c)(2)(A).
- 81. Together with a coalition of beekeepers and public interest groups, Plaintiff Beyond Pesticides delivered a letter to Defendants dated December 8, 2010, requesting suspension of clothianidin's registration due to inadequate data on impacts to pollinators and excessive agency delay in ensuring compliance with that condition.¹² By letter of February 18, 2011, Defendants refused that suspension request.¹³

¹² See Letter from Beyond Pesticide et al., supra note 1.

¹³ See Letter from Steven Bradbury, supra note 2.

Plaintiffs CFS, Beyond Pesticides, Steve Ellis, and Tom Theobald, along with a

1 2 coalition of beekeepers and honey producers, and other public interest groups, submitted the 3 Clothianidin Legal Petition to EPA to suspend the registration of clothianidin on March 20, 2012 (Docket No. EPA-HQ-OPP-2012-0334), rooted in the nine-year unreasonable delay in ensuring 4 full compliance with the "conditional registration" conditions for clothianidin products. ¹⁴ They 5 followed that Petition with two supplemental filings, dated May 3, 2012, and June 18, 2012, 6 respectively. 15 These consisted of information that came to light after the Petition was filed, 7 8 including critical new data on how certain uses of clothianidin constitute an "imminent hazard" 9 to honey bees and other beneficial insects that compelled a decision to promptly suspend

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clothianidin's registration.

- 83. By letter dated July 17, 2012, Defendants denied the portion of the Petition that alleged an "imminent hazard" existed. 16 That letter indicated EPA did not consider the May 3, 2012 and June 18, 2012 supplemental filings in making that decision. To date, the agency has yet to issue a decision based on the supplemental evidence showing imminent hazard or on any of the other new science and extensive mass honey bee kill data that emerged after the Petition was filed.
- Defendant Bradbury's letter of July 17, 2012, stated his denial of the imminent 84. hazard claim in the Petition was EPA's "final action pursuant to section 16 of FIFRA" with respect to that claim. There was no Federal Register notice, no public hearing, and no opportunity for notice and comment prior to this final action. The EPA has yet to resolve any of the remaining claims in the Petition or to reconsider its denial of an "imminent hazard" based on the full administrative record before it.
- 85. The evidence Plaintiffs provided in the Clothianidin Legal Petition and in their supplemental filings described an "unreasonable adverse effect on the environment" in terms of

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¹⁴ See Clothianidin Legal Petition, supra note 3.

¹⁵ On file with Plaintiff CFS; see Docket No. EPA-HQ-OPP-2012-0334, available at http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2012-0334.

¹⁶ See Letter from Steven Bradbury, supra note 4.

a vast number of bee kills impacting likely many hundreds of U.S. and Canadian colonies and tens of millions of valuable honey bees. These acute bee kills, which were ongoing during EPA's decision-making period on the Petition, are in addition to the ongoing chronic impacts of clothianidin. EPA's July 17, 2012 letter admitted the agency did not consider the ongoing bee kills associated with spring corn planting or any other information received after May 3, 2012, including the numerous clothianidin-related bee kills during the ten weeks between May 3, 2012 and July 17, 2012.

- 86. Additionally, EPA's response letter and related documentation showed the agency did not conduct any analysis of clothianidin's effects on endangered or threatened species and failed to consult with FWS regarding its final agency action denying an imminent hazard.
- 87. Virtually all the information Plaintiffs have filed with respect to the various risks of clothianidin also apply to its precursor compound, the very similar insecticide thiamethoxam.
- 88. On October 16, 2012, Plaintiffs CFS, Beyond Pesticides, and Steve Ellis delivered a letter to Defendants on thiamethoxam, setting forth how that compound raises risks that are essentially equivalent to the risks of clothianidin and seeking a suspension of its registration as well.¹⁷ That letter cited to new evidence about the dangers of thiamethoxam, including direct bee kills suffered by Plaintiff Steve Ellis that EPA itself attributed to thiamethoxam and/or clothianidin in an official Incident Report. While EPA acknowledged receipt of the letter, by a response letter to CFS dated February 27, 2013, EPA has refused that suspension request also.¹⁸
- 89. On September 6, 2012, Plaintiffs CFS, Beyond Pesticides, the Sierra Club, Steve Ellis, and Tom Theobald filed a "Sixty-Day Notice of Intent to Sue Pursuant to the Endangered Species Act regarding Registration and Use Approvals of Clothianidin and Thiamethoxam, Neonicotinoid Insecticides," with Defendant Perciasepe's predecessor (Lisa Jackson) and Ken Salazar, the former Secretary of the Interior, U.S. Department of the Interior. ¹⁹ More than sixty

¹⁷ See Letter from Plaintiffs, supra note 5.

¹⁸ See Letter from EPA, supra note 6.

¹⁹ See Sixty-Day Notice Letter, supra note 7.

days have passed since the Sixty-Day Notice Letter, which sought suspension of the registrations involved, and neither EPA nor the Department of the Interior has responded or resolved the ongoing ESA violation concerns raised in the Sixty-Day Notice Letter.

EPA Registration Process Facts

90. More than ten years ago, in February 2003, EPA issued a Risk Assessment for clothianidin seed treatment for corn and canola. EPA scientists raised serious concerns about the compound and called for a field test evaluating its environmental hazards prior to registration, specifically citing harm to pollinators:

The possibility of toxic exposure to nontarget pollinators through the translocation of clothianidin residues that result from seed treatment (corn and canola) has prompted EFED [the EPA Environmental Fate and Effects Division] to require field testing that can evaluate the possible chronic exposure to honey bee larvae and queen. In order to fully evaluate the possibility of this toxic effect, a complete worker bee life cycle study must be conducted, as well as an evaluation of exposure and effects to the queen.²¹

91. Less than two months later, in its Addendum to the Risk Assessment in April 2003, EPA reversed this position, recommending conditional registration while the registrant arranged for the required chronic exposure study. In contrast to its prior memorandum, EPA decided it would allow the nationwide sale and use of clothianidin while the registrant arranged for the study necessary to determine whether its decision would be a grave mistake. EPA provided no reason for its reversal; however, the second memorandum confirmed that EPA determined a study evaluating the long term toxicity to pollinators was necessary as a condition for registration. To date, for clothianidin, the requirement of a complete and adequate life cycle study, and evaluation of exposure and effects to the queen bee, remains unmet. This also applies in the case of thiamethoxam, as EPA's pollinator field test conditions for it incorporated and mirrored the conditions imposed for clothianidin.

²⁰ Memorandum: Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola, PC Code 044309, EPA Environmental Fate and Effects Division 2 (Feb. 20, 2003), *available at* http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-044309_20-Feb-03_a.pdf.

 $^{^{21}}$ *Id.* at 2.

On June 20, 2012, without a hearing, EPA issued a conditional registration to

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Syngenta Crop Protection for CruiserMaxx Vibrance Cereals, produced from thiamethoxam.

The approval document states:

Field Test for Pollinators (test guideline 850[.]3040)[:] An acceptable study must be submitted or cited no later than the time this study is required to be submitted or cited for current thiamethoxam registrations.²²

93. This is a vague condition in violation of the FIFRA's conditional registration requirements because it neither sets nor refers to any limited time period for submitting the pollinator field test study originally required nine years prior. It refers to an alleged "time this study is required to be submitted or cited for current thiamethoxam registrations" when there is no defined period to satisfy the pollinator study condition for the other thiamethoxam

registrations.²³ EPA's language violates the FIFRA requirement that periods for compliance with conditions must be "limited" and is vague, unenforceable, and arbitrary and capricious. On information and belief, numerous other thiamethoxam and clothianidin use approvals have the

same defects.

94. In the case of clothianidin's approval for use on corn and canola, since 2003, at least the following additional conditions based on data gaps, beyond the field test for pollinators, have remained unsatisfied, according to the most recent EPA records available to Plaintiffs: a) Whole Sediment Acute Toxicity Invertebrates, Freshwater; b) Whole Sediment Acute Toxicity Invertebrates, Estuarine and Marine; c) Aerobic Aquatic Metabolism; d) Seed Leaching Study; and e) Small-Scale Prospective Groundwater Monitoring Study. Numerous other conditions and data gaps also remain unsatisfied. The available records are less clear for thiamethoxam, but the same defects appear to exist as for clothianidin. Some of these conditions were to have been met within three years after being first imposed in 2003 for clothianidin, and two years after being first imposed in 2000 for thiamethoxam. Those clothianidin conditions thus are still not met—up

²² EPA, Notice of Pesticide Registration, June 20, 2012, *available at* http://www.epa.gov/pesticides/chem_search/ppls/000100-01383-20120620.pdf. ²³ *Id.*

to seven years after their deadline, and the thiamethoxam conditions are still not met—up to eleven years after their deadline.

- 95. Ten to thirteen years exceeds the amount of time reasonably sufficient to generate the data needed to satisfy the conditions imposed on the variety of clothianidin and thiamethoxam products in Appendices A and B, and for EPA to decide the registrations must be suspended until the conditions are satisfied. *See* 7 U.S.C. § 136a(c)(7)(A). Delays of seven to eleven years past the original EPA-imposed deadlines are unreasonable and violate FIFRA's conditional registration requirements.
- 96. EPA's Registration Review process for thiamethoxam recognizes that, thirteen years after it first approved uses of this compound, the agency still lacks vital information about its environmental effects. The EPA Registration Review "Thiamethoxam Final Work Plan" admits the environmental fate database is "only partially fulfilled and several ecological effects data gaps were also identified." ²⁴ It then lists at least twenty-five tests, studies, and other data requirements that must be fulfilled, including, but not limited to, such basic information as:

850.2100 - Avian oral toxicity with a passerine

850.3030 - Honey bee toxicity of residues on foliage study

850.3040 – Field test for pollinators

850.1735 – Whole sediment acute toxicity invertebrates, freshwater

Special Study – Larval toxicity study (honey bee)

Special Study – Residues, pollen and nectar

Special Study – Laboratory (chronic) pollinator feeding study (honey bee)²⁵

- 97. The Registration Review documents for clothianidin show substantially identical information gaps. The minimum level of knowledge required under the conditional registration provisions of the FIFRA to protect honey bees, other beneficial insects, and ecosystems generally, from unreasonable adverse effects caused by these two insecticides, does not exist.
 - 98. EPA's Registration Review process aims for the year 2018, per the agency's

²⁴ EPA, Thiamethoxam Final Work Plan for Registration Review, June 2012, *available at* http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0581-0024.

current schedule, before making a decision on the appropriateness of thiamethoxam's and clothianidin's continuing registrations. Several Plaintiffs have formally commented on the dockets for these reviews, stating the schedule is unreasonably slow and inadequate in light of known risks, and urging EPA to commit to completing the reviews no later than the end of 2013, but EPA has refused. EPA has provided no indication that it will fully decide on the pending Clothianidin Legal Petition to suspend clothianidin's registration prior to 2018.

- 99. Instead, EPA has continued to allow the sale and use of multiple clothianidin and thiamethoxam products even though the registrants failed to satisfy essential registration conditions imposed as early as 2000 that are necessary to support the required "no unreasonable adverse effects on the environment" determination. These conditions are not limited to pollinator field tests; however, the failure to obtain an adequate field test of the impacts of clothianidin or thiamethoxam likely is the most serious source of EPA's injury to the Beekeeper and Honey Producer Plaintiffs.
- 100. Available EPA records as of November 2012, indicated approximately eleven "pending" outdoor use approvals for clothianidin and thiamethoxam. On information and belief, these include the following registration numbers and names, but others may exist:

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Clothianidin
#73049-UIE – VBC3
#73049-UOR – Clothianidin 7.5 MC
#08NC01 – [unnamed]
Thiamethoxam
#100-RUER – A16901B CP
#100-RUEE – Mainspring Insecticide
#100-RUEU – A16901B Turf
#100-RUUU – CruiserMAXX Potato Extreme
#100-RULT – Avicta Complete Beans 500
#100-RULI – Endigo ZCX
#100-RULO – SYT0113
#100-RUAN – SYT0511
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101. The agency is likely to approve all of these proposed future uses under its conditional registration review process. 7 U.S.C. § 136a(c)(7). They present the same general risks to Plaintiffs and the environment and the same FIFRA and ESA violations as the already-approved uses.

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FIRST CLAIM

EPA's Denial of Imminent Hazard from Clothianidin Products Violated the APA

- 102. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 101, as though fully alleged herein.
- 103. EPA's final agency action, in denying an "imminent hazard" existed in response to Plaintiff's Clothianidin Legal Petition, failed to consider any of Plaintiffs' supplemental filings, the bee kills associated with spring corn planting, or any other information it received after May 3, 2012. Ignoring this information available to the agency, including the hundreds of ongoing clothianidin-related bee kills during the ten week period between May 3 and July 17, 2012, when EPA issued its decision, was arbitrary and capricious. *See* 5 U.S.C. § 706(2).
- 104. The agency did not fully consider the likelihood of an imminent hazard recurring during the time required for a cancellation or change in classification proceeding, under 7 U.S.C. § 136d(c)(1). The time for such a proceeding is likely up to two years. It was, and remains, foreseeable that hundreds of additional bee kills will be suffered by Plaintiffs and others in the now ongoing 2013 and 2014 spring planting seasons because of EPA's failure to respond based on the full 2012 spring bee kill information. EPA's arbitrary and capricious actions violated the APA, and its failure to reconsider its imminent hazard determination to date, more than one year after the Petition was filed, in view of the risks presented, constitutes unreasonable delay under the APA. See 5 U.S.C. § 706(1).
- 105. EPA's denial of "imminent hazard" has damaged and continues to damage Plaintiffs. Plaintiff beekeepers are suffering severe ongoing economic and personal damages. EPA allowed clothianidin products that are harmful to Plaintiffs to be used that EPA should have suspended; in particular, EPA allowed the continued use of clothianidin seed treatment products that foreseeably would damage the survival of the Beekeeper and Honey Producers' bees during 2013 and 2014.

SECOND CLAIM

EPA's Denial of Imminent Hazard for Clothianidin Products Violated the ESA and the APA

- 106. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 105, as though fully alleged herein.
- 107. EPA's final agency action, in denying an "imminent hazard" existed in response to Plaintiff's' Clothianidin Legal Petition, was arbitrary and capricious. EPA's determination that no unreasonable hazard existed to endangered or threatened species, violated the ESA and the APA. The FIFRA's definition of "imminent hazard" includes whether the pesticide "involves unreasonable hazard to the survival of a species declared endangered or threatened by the Secretary [of the Interior] pursuant to the [ESA]." 7 U.S.C. § 136(l). EPA failed to prepare the required effects analysis or to consult with FWS regarding impacts on endangered or threatened species in its final agency action denying an imminent hazard.
- 108. In addition, EPA's continuing authority over conditional and unconditional clothianidin product registrations constitutes ongoing action, and it has violated its continuing obligation to consider effects on endangered species in determining whether an imminent hazard exists. New scientific information, including the supplemental bee kill data and other scientific information submitted by Petitioner Plaintiffs that EPA failed to consider, shows effects of clothianidin on invertebrates and ecosystems and compels an ESA effects determination and consultation with FWS. EPA's failure to consider effects on endangered species or consult with FWS was arbitrary and capricious.
- 109. EPA's actions violated § 7(a) of the ESA and were arbitrary and capricious actions under the APA. 5 U.S.C. § 706(2). EPA allowed clothianidin products that are harmful to endangered and threatened species to continue to be used, which EPA should have suspended, and damaged Plaintiffs' interest in avoiding jeopardy to the survival of ESA-listed species and preventing adverse modification of their designated critical habitats.

THIRD CLAIM

EPA's Failure to Publish Notices of Pesticide Applications for Clothianidin Products Violated the FIFRA and the APA

- 110. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 109, as though fully alleged herein.
- 111. For the vast majority of clothianidin registrations and changed use approvals, EPA did not, as required, announce a "notice of receipt of application" or a "notice of issuance" in the Federal Register or in any other public order or hearing.
- 112. As indicated in Appendix A, on information and belief, only four clothianidin registrations had any Federal Register notice of application and none had a notice of issuance. On information and belief, EPA issued the following clothianidin new use registrations without first publishing notices of application or issuance in the Federal Register, in violation of 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102:

EPA Registration Number	Date of Initial Registration
66330-365	10/18/2007
66330-366	10/18/2007
66330-367	10/18/2007
66330-368	10/18/2007
72155-82	01/28/2008
72155-94	08/24/2009
72155-95	07/30/2009
72155-96	12/28/2009
264-789	05/30/2003
264-846	05/30/2007
264-984	07/01/2003
264-1034	11/14/2006
264-1035	12/14/2006
264-1056	03/07/2008
264-1079	11/21/2008
264-1081	04/28/2010
264-1082	01/29/2010
264-1109	03/16/2010
264-1121	05/11/2012
	Number 66330-365 66330-366 66330-367 66330-368 72155-82 72155-94 72155-95 72155-96 264-789 264-846 264-984 264-1034 264-1035 264-1079 264-1081 264-1082 264-1109

	Emesto Quantum	264-1125	05/11/2012
	Poncho/GB 126	264-1132	04/29/2011
	VBC3 Insecticide	73049-482	09/25/2012
	Darlex Insecticide	73049-467	03/18/2010
	V-10170 16 WSG Insecticide	59639-153 / 66330-52	02/23/2005
	Arena 0.5G	59639-156 / 66330-53	11/30/2004
.	V-10170 0.25G Insecticide	59639-157 / 66330-70	10/02/2006
	V-10170 0.25G GL Insecticide	59639-164	01/27/2009
	Inovate Seed Protectant	59639-176	06/21/2011
	NipsIt Suite Cereals of Seed Protectant	59639-183	12/21/2011
	NipsIt Suite Canola Seed Protectant	59639-184	01/06/2012
'	Inovate Neutral Seed Protectant	59639-187	01/25/2012
	movaic redutal seed froiectant	37037-107	

Thus, a number of approvals lacked the public notice and opportunity for public comment required under 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102. Those approvals included new clothianidin uses on crops and habitats where Beekeeper and Honey Producer Plaintiffs' honey bees foraged and pollinated. Additionally, on information and belief, for each of the clothianidin insecticide uses and products, EPA also failed to meet this requirement: "within 30 days after the Administrator registers a pesticide under this Act the Administrator shall make available to the public the data called for in the registration statement." 7 U.S.C. § 136a(c)(2)(A).

- 113. EPA's failure to provide Plaintiffs with the FIFRA-mandated notices of application and issuance for the clothianidin registrations and changed uses in the Federal Register, its denial of public comment opportunities, and its failure to make its registration data available to the public within thirty days, denied Plaintiffs and the public the ability to submit information to EPA that may have convinced the agency not to issue those approvals in the first instance, or to cancel them after they were issued, and denied Plaintiff Beekeepers knowledge that would have allowed them to protect their honey bees. EPA allowed the use of products that cause unreasonable adverse effects and are harmful to Plaintiffs.
- 114. EPA's failure to publish the Federal Register notices as required under 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102, or to provide data required under 7 C.F.R. § 136a(2)(A), establishes that these clothianidin products were approved "without observance of procedure required by law," in violation of the APA. 5 U.S.C. § 706(2)(D).

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FOURTH CLAIM

EPA's Failure to Publish Notices of Pesticide Applications for Thiamethoxam Products Violated the FIFRA and the APA

- 115. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 114, as though fully alleged herein.
- For the vast majority of thiamethoxam registrations and changed use approvals, 116. EPA did not, as required, announce a "notice of receipt of application" or a "notice of issuance" in the Federal Register or in any other public order or hearing.
- 117. As indicated in Appendix B, on information and belief, EPA issued the following thiamethoxam new use registrations without first publishing notices of application or issuance in the Federal Register, in violation of 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102:

12	Thiamethoxam Product Name	EPA Registration Number	Date of Initial Registration
13	Xamox Technical	43813-29	10/21/2002
	Xamox 30L	43813-30	07/28/2006
14	Xamox 10TK	43813-31	05/30/2006
15	Xamox 100 SL	43813-36	05/23/2006
	Dyna-Shield Thiamethoxam Fungicide	34704-939	07/10/2006
16	Agita 1GB Fly Bait	70585-9	12/08/2010
	Agita 10 WG	70585-10	12/08/2010
17	Helix XTra Insecticide with Fungicides	100-935	12/04/2000
	Actara Insecticide	100-938	05/17/2001
18	Platinum Insecticide	100-939	05/17/2001
19	Cruiser Insecticide	100-941	12/04/2000
	Meridian 25WG	100-943	02/15/2007
20	Flagship 25WG	100-955	07/30/2003
	Flagship 0.22G	100-960	02/23/2007
21	Meridian 0.33G	100-961	02/23/2007
	Helix Insecticide with Fungicides	100-973	12/04/2000
22	Platinum Ridomil Gold	100-974	05/17/2001
23	Centric 40WG	100-1147	04/11/2002
23	Cruiser XL Insecticide and Fungicide PrePack	100-1184	02/05/2004
24	Cruiser Extreme	100-1208	03/28/2005
	Thiamethoxam 240 SC Manufacturing Use Product	100-1246	09/6/2006
25	CruiserMaxx	100-1247	05/24/2006
26	CruiserMaxx Potato Insecticide and Fungicide	100-1248	05/25/2006
20	Adage - Maxim 4FS Twinpack	100-1249	04/14/2006
27	Actara 240 SC Insecticide	100-1250	01/18/2007
	Optigard Ant Gel Bait	100-1260	04/4/2007
28	Thiamethoxam Ant Killer Gel	100-1261	04/4/2007

1	Endigo ZC	100-1276	08/21/2007	
1	THX/MXM/FDL CZ	100-1283	09/20/2007	
2	Thiamethoxam Lawn & Landscape 0.33G	100-1288	11/02/2007	
_	Thiamethoxam Lawn & Landscape 0.22G	100-1289	11/02/2007	
3	Platinum 75 SG Insecticide	100-1291	01/17/2008	
	Thiamethoxam 0.02/Lambda-Cyhalothrin	100-1304	04/04/2008	
4	CruiserMaxx Cereals	100-1305	04/16/2008	
	Durivo	100-1318	08/26/2008	
5	Voliam Flexi Insecticide	100-1319	08/25/2008	
6 7	Avicta Duo	100-1321	10/31/2008	
	Thiamethoxam 0.40/Lambda-cyhalothrin 0.16 ME	100-1334	05/12/2009	
	Concentrate			
	Thiamethoxam 0.010/Lambda-cyhalothrin 0.004	100-1336	05/12/2009	
8	ME RTU			
9	Meridian 0.20G	100-1341	06/22/2009	
	Meridian 0.14G	100-1346	07/01/2009	
10	Agri-Flex Miticide/Insecticide	100-1350	04/06/2010	
10	Avicta Duo 250	100-1353	10/27/2009	
11	Cruiser PD Insecticide	100-1365	08/05/2011	
	Difenoconazole 0.170/Thiamethoxam	100-1366	08/05/2011	
12	0.010/Lambda-cyhalothrin 0.004 ME RTU			
10	Difenoconazole 0.66/Thiamethoxam 0.40/Lambda-	100-1367	08/05/2011	
13	cyhalothrin 0.16 ME Concentrate			
14	CruiserMaxx Rice	100-1369	07/20/2010	
17	Optigard Liquid Ant Bait	100-1370	08/02/2010	
15	Cruisermaxx Vibrance Cereals	100-1383	06/20/2012	
	Four-Way VAP	100-1384	10/29/2010	
16	Avicta Complete Corn 500	100-1399	06/15/2011	
17	Avicta Complete Corn 250	100-1405	10/19/2011	
17	Caravan G	100-1415	01/11/2012	
18	THX_MXM_FDL_TBZ FS	100-1426	02/02/2012	
	CruiserMaxx EZ	100-1427	02/02/2012	
19	Derby	100-1436	04/23/2012	
	Tandem	100-1437	04/23/2012	
20	CruiserMaxx Peanuts	100-1438	04/30/2012	
21	Solvigo Miticide/Insecticide	100-1440	06/21/2012	
21	Adage Delux	100-1449	08/23/2012	
22	Adage Premier	100-1450	08/23/2012	
	Avicta complete beans	100-1457	01/15/2013	
23	Endigo ZCX	100-1458	01/23/2013	
	SYT0511	100-1460	01/30/2013	
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25	A large number of the listed pesticides products above	e are not potentially co	overed under any	
23	ior notice of application that was published in the Federal Register. Thus, the vast majority of			
26	prior notice of application that was published in the Federal Register. Thus, the vast majority o			
27	approvals lacked the public notice and opportunity for public comment required under 7 U.S.C.			
28	§ 136a(c)(4) and 40 C.F.R. § 152.102. Those approvals included new thiamethoxam uses on			

crops and habitats where the Beekeeper and Honey Producer Plaintiffs'honey bees foraged and pollinated. On information and belief, for each of the thiamethoxam insecticide uses and products, EPA also failed to meet this requirement: "within 30 days after the Administrator registers a pesticide under this Act the Administrator shall make available to the public the data called for in the registration statement." 7 U.S.C. § 136a(c)(2)(A).

- application and issuance for the thiamethoxam registrations and changed uses in the Federal Register, its denial of public comment opportunities, and its failure to make its registration data available to the public within thirty days, denied Plaintiffs and the public the ability to submit information to EPA that may have convinced the agency not to issue those approvals in the first instance, or to cancel them after they were issued, and denied Plaintiff Beekeepers knowledge that would have allowed them to protect their honey bees. EPA has allowed the uses of products that cause unreasonable adverse effects and are harmful to Plaintiffs.
- 119. EPA's failure to publish the Federal Register notices as required under 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102, or to provide data required under 7 C.F.R. § 136a(2)(A), establishes that these thiamethoxam products were approved "without observance of procedure required by law," in violation of the APA. 5 U.S.C. § 706(2)(D).

FIFTH CLAIM

EPA Violated the FIFRA Conditional Registration Requirements and the APA for Conditionally-Registered Clothianidin Products

- 120. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 119, as though fully alleged herein.
- 121. On information and belief, of the registered uses of clothianidin identified in Appendix A, approximately twenty-three registrations are still registered as "conditional." A reasonable time for the conditions on these product registrations to be met, including but not limited to the adequate pollinator field study condition, has long passed. EPA has been arbitrary and capricious and violated the FIFRA's conditional registration provisions, which require compliance with conditions imposed within a limited, reasonable period. The FIFRA language

is mandatory, providing EPA "shall issue a notice of intent to cancel a [conditional] registration . . . if . . . at the end of the period provided for satisfaction of any condition imposed, that condition has not been met." 7 U.S.C. § 136d(e)(1) (emphasis added). EPA's own regulations are clear that the time for compliance is limited. *See* 40 C.F.R. § 152.114-115. On information and belief, the original EPA-imposed deadlines for meeting the conditions—three years in the case of clothianidin's initial product registration—have been violated. On information and belief, EPA has unreasonably delayed for up to nine years in some cases and failed to issue any such notice for these approximately twenty-three conditional registrations.

- 122. EPA has allowed impermissibly vague conditions for conditional registrations that neither state nor refer to a limited time period for achievement. In some cases, such as the pollinator field test study, EPA has, without a hearing, placed the conditions "in reserve," with no time period for achieving them, which violates the conditional registration requirements. Despite repeated formal requests from the Plaintiffs, the Defendants' duty to ensure compliance with the clothianidin registration conditions has been unlawfully withheld and unreasonably delayed, in violation of the FIFRA, 7 U.S.C. § 136a(c)(7), and the APA, 5 U.S.C. § 706(1).
- 123. EPA's actions have damaged Plaintiffs. EPA's failure to timely ensure compliance with the registration conditions it imposed has allowed clothianidin products that cause unreasonable adverse effects and are harmful to Plaintiffs to continue to be used, products that EPA should have suspended.

SIXTH CLAIM

EPA Violated the FIFRA Conditional Registration Requirements and the APA for Conditionally-Registered Thiamethoxam Products

- 124. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 123, as though fully alleged herein.
- 125. On information and belief, of the registered uses of thiamethoxam identified in Appendix B approximately fifty-four registrations are still registered as "conditional." A reasonable time for the conditions on these product registrations to be met, including but not limited to the adequate pollinator field study condition, has long passed. EPA has been arbitrary

and capricious and violated the FIFRA's conditional registration provisions, which require compliance with conditions imposed within a limited, reasonable period. The FIFRA language is mandatory, providing EPA "shall issue a notice of intent to cancel a [conditional] registration ... if ... at the end of the period provided for satisfaction of any condition imposed, that condition has not been met." 7 U.S.C. § 136d(e)(1) (emphasis added). EPA's own regulations are clear that the time for compliance is limited. *See* 40 C.F.R. § 152.114-115. On information and belief, the original EPA-imposed deadlines for meeting the conditions—two years in the case of thiamethoxam's initial product registration—have been violated On information and belief, EPA has unreasonably delayed for up to eleven years in some cases and failed to issue any such notice for these approximately fifty-four conditional registrations.

- 126. EPA has allowed impermissibly vague conditions for conditional registrations that neither state nor refer to a limited time period for achievement. In some cases, such as the pollinator field test study, EPA has, without a hearing, placed the conditions "in reserve," with no time period for achieving them, which violates the conditional registration requirements. Despite repeated formal requests from the Plaintiffs, the Defendants' duty to ensure compliance with the thiamethoxam registration conditions has been unlawfully withheld and unreasonably delayed, in violation of the FIFRA, 7 U.S.C. § 136a(c)(7), and the APA, 5 U.S.C. § 706(1).
- 127. EPA's actions have damaged Plaintiffs. EPA's failure to timely ensure compliance with the registration conditions it imposed has allowed thiamethoxam products that cause unreasonable adverse effects and are harmful to Plaintiffs to continue to be used, products that EPA should have suspended.

SEVENTH CLAIM

EPA Violated the FIFRA Requirements and the APA for Unconditionally-Registered Clothianidin Products

- 128. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 127, as though fully alleged herein.
- 129. EPA has unconditionally registered numerous clothianidin products for outdoor use despite missing data on this pesticide. EPA's classification of clothianidin products as

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unconditional, despite outstanding data gaps and conditions, violates the FIFRA's provisions for unconditional registration. Compare 7 U.S.C. § 136a(c)(5) with 7 U.S.C. § 136a(c)(7).

- 130. For example, on April 22, 2010, without a hearing, EPA notified Valent U.S.A. Corporation that its Clothianidin Technical product, which is the foundation for clothianidin formulations and was previously conditionally registered, was reclassified to unconditional. On information and belief, numerous other clothianidin product uses were similarly reclassified. For Clothianidin Technical and all other products whose registrations are no longer conditional, the removal or lifting of the conditions was arbitrary and capricious and in violation of the FIFRA's conditional registration provisions because the conditions were not fully met before they were removed.
- 131. On information and belief, EPA has classified fourteen clothianidin products are as unconditional despite the failure of the registrants to fill existing data gaps and comply with the past conditions, including at least the following registration numbers and names:

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Clothianidin
# 264-984 – Titan FL
# 264-1121 – Prosper Evergol
# 264-1125 – Emesto Quantum
# 59639-153 - V-10170 16 WSG insecticide
# 59639-156 - Arena 0.5 G
# 59639-173 – V-10170 0.25 G insecticide
# 59639-176 – Inovate seed protectant
# 59639-183 – Nipsit suite cereals of seed protectant
# 59639-184 – Nipsit suite canola seed protectant
# 59639-187 – Inovate neutral seed protectant
# 72155-96 – Insecticide TD Granule
#73049-467 – Darlex insecticide
#FL 11001 - Arena 50 WDG Insecticide
# ID 060015 - Poncho 600
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None of these products otherwise meet the criteria for unconditional registration.

132. EPA's classification of these clothianidin products as unconditional registrations while maintaining the conditional registrations for numerous other clothianidin products is inconsistent, arbitrary, capricious, and is in violation of the FIFRA's requirements for conditional registrations and the APA. EPA's actions alleged herein contradicted the earlier

requests by Plaintiffs that the condition classifications be maintained and that full compliance with the pollinator field test condition, in particular, be compelled. Further, EPA's action of issuing unconditional registrations despite a preponderance of evidence that these clothianidin products, when used in accordance with widespread and commonly recognized practice, cause unreasonable adverse effects on the environment, violated the FIFRA and the APA.

133. EPA's actions have damaged Plaintiffs. EPA's failure to fully enforce the conditions it imposed has allowed clothianidin products that cause unreasonable adverse effects and are harmful to Plaintiffs to continue to be used, products that EPA should have suspended.

EIGHTH CLAIM

EPA Violated the FIFRA Requirements and the APA for Unconditionally-Registered Thiamethoxam Products

- 134. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 133, as though fully alleged herein.
- 135. EPA has unconditionally registered numerous thiamethoxam products despite missing data on this pesticide. EPA's classification of these thiamethoxam products as unconditional, despite outstanding data gaps and conditions, violates the FIFRA's provisions for unconditional registration. *Compare* 7 U.S.C. § 136a(c)(5) *with* 7 U.S.C. § 136a(c)(7).
- 136. For all thiamethoxam products whose registrations are no longer conditional, the removal or lifting of the conditions was arbitrary and capricious and in violation of the FIFRA's conditional registration provisions because the conditions were not fully met before they were removed.
- 137. On information and belief, EPA classified seven thiamethoxam products as <u>un</u>conditional despite the failure of the registrants to fill data gaps and meet missing conditions, including at least the following registration numbers and names:

Thiamethoxam

- # 100-1184 Cruiser XL insecticide and fungicide prepack
- # 100-1246 Thiamethoxam 240 SC manufacturing product
- # 100-1365 Cruiser PD insecticide
- # 100-1369 Cruisermaxx rice
- # 100–1405 Avicta complete corn

100-1415 – Caravan G # 34704-939 – Dyna-shield thiamethoxam fungicide

None of these products otherwise meet the criteria for unconditional registration.

- 138. EPA's classification of these products as unconditional registrations while maintaining the conditional registrations and outstanding data requirements on numerous other thiamethoxam products is inconsistent, arbitrary, capricious, and is in violation of the FIFRA's requirements for conditional registrations and the APA. EPA's actions alleged herein contradicted the earlier requests by Plaintiffs that the condition classifications be maintained and that full compliance with the pollinator field test condition, in particular, be compelled. Further, EPA's actions of issuing unconditional registrations despite a preponderance of evidence that these thiamethoxam products, when used in accordance with widespread and commonly recognized practice, cause unreasonable adverse effects on the environment, violated the FIFRA and the APA.
- 139. EPA's actions have damaged Plaintiffs. EPA's failure to fully enforce the conditions it imposed has allowed thiamethoxam products that cause unreasonable adverse effects and are harmful to Plaintiffs to continue to be used, products that EPA should have suspended.

NINTH CLAIM

EPA is Violating the FIFRA Suspension Requirements and the APA for Clothianidin Products

- 140. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 139, as though fully alleged herein.
- 141. When used in accordance with widespread and commonly recognized practice, clothianidin currently causes unreasonable adverse effects on the environment.
- The legal burden of showing that any pesticide and any approved uses meet the FIFRA criteria to be eligible for continued registration rests with the products' proponents. *See* 40 C.F.R. § 154.5. The proponents of clothianidin's numerous uses have not met that burden.
- 143. Plaintiffs have repeatedly formally requested EPA to suspend the registrations for clothianidin products, listed in Appendix A, and the agency has refused. EPA's failure to

suspend the registrations of these products in view of their unreasonable adverse effects violates the FIFRA, 7 U.S.C. § 136d(b), and the APA, 5 U.S.C. § 706(1)-(2).

144. EPA's actions are damaging Plaintiffs as previously stated herein. EPA's ongoing failure to suspend the clothianidin registrations is allowing these products, which cause unreasonable adverse effects and are harmful to Plaintiffs, to continue to be used without restrictions across the nation.

TENTH CLAIM

EPA is Violating the FIFRA Suspension Requirements and the APA for Thiamethoxam Products

- 145. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 144, as though fully alleged herein.
- 146. When used in accordance with widespread and commonly recognized practice, thiamethoxam currently causes unreasonable adverse effects on the environment.
- 147. The legal burden of showing that any pesticide and any approved uses meet the FIFRA criteria to be eligible for continued registration rests with the products' proponents. *See* 40 C.F.R. § 154.5. The proponents of thiamethoxam's numerous uses have not met that burden.
- 148. Plaintiffs have repeatedly formally requested EPA to suspend the registrations for thiamethoxam products, listed in Appendix B, and the agency has refused. EPA's failure to suspend the registrations of these products in view of their unreasonable adverse effects violates the FIFRA, 7 U.S.C. § 136d(b), and the APA, 5 U.S.C. § 706(1)-(2).
- 149. EPA's actions are damaging Plaintiffs as previously stated herein. EPA's ongoing failure to suspend the thiamethoxam registrations is allowing these products, which cause unreasonable adverse effects and are harmful to Plaintiffs, to continue to be used without restrictions across the nation.

ELEVENTH CLAIM

EPA Violated the FIFRA's Labeling Requirements for Clothianidin Products

150. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 149, as though fully alleged herein.

- 151. Clothianidin product labels have warnings about bee hazards generally; however, they are inadequate and inconsistent across various registered products. The label warnings, even if followed, violate labeling requirements as they do not advise the farmer, applicator, or other user how to avoid the harms that the labels acknowledge and are not "adequate to protect health and the environment," in violation of the FIFRA. 7 U.S.C. § 136(q)(1)(F).
- 152. One such harm is contaminated dust from planting of treated seeds, a source of repeated major beekills for which EPA lacks authority to effectively enforce label warnings in ways that can prevent the kills from reoccurring. EPA has admitted current labeling is inadequate. It is arbitrary and capricious for EPA to continue to rely on inconsistent product labels that are inadequate to fully warn of clothianidin's environmental risks and that the agency lacks the ability to enforce.
- 153. EPA's actions have damaged Plaintiffs. EPA's failure to comply with the FIFRA's labeling requirements has allowed uses of clothianidin products according to their labels in ways that that are harmful to Plaintiffs. Such harms would be avoided if the products included consistent, adequate warnings and directions.

TWELFTH CLAIM

EPA Violated the FIFRA's Labeling Requirements for Thiamethoxam Products

- 154. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 153, as though fully alleged herein.
- 155. Thiamethoxam product labels have warnings about bee hazards generally; however, they are inadequate and inconsistent across various registered products. The label warnings, even if followed, violate labeling requirements as they do not advise the farmer, applicator, or other user how to avoid the harms that the labels acknowledge and are not "adequate to protect health and the environment," in violation of the FIFRA. 7 U.S.C. § 136(q)(1)(F).
- 156. One such harm is contaminated dust from planting of treated seeds, a source of repeated major beekills for which EPA lacks authority to effectively enforce label warnings in ways that can prevent the kills from reoccurring. EPA has admitted current labeling is

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inadequate. It is arbitrary and capricious for EPA to continue to rely on inconsistent product labels that are inadequate to fully warn of thiamethoxam's environmental risks and that the agency lacks the ability to enforce.

157. EPA's actions have damaged Plaintiffs. EPA's failure to comply with the FIFRA's labeling requirements has allowed uses of thiamethoxam products according to their labels in ways that that are harmful to Plaintiffs. Such harms would be avoided if the products included consistent, adequate warnings and directions.

THIRTEENTH CLAIM

EPA's Actions in Approving Clothianidin Products and Labels Violated the ESA

- 158. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 157, as though fully alleged herein.
- 159. Prior to registering the approximately thirty-five clothianidin products listed in Appendix A over the last ten-year period, EPA violated Section 7 of the ESA by failing to: a) ensure, in consultation with FWS, that the EPA-approved uses of clothianidin would not be likely to jeopardize the continued existence of any threatened or endangered species or result in the destruction or adverse modification of the critical habitat of such species; b) request from FWS information on whether any threatened or endangered species, or designated critical habitat, may be present within or near the areas of the proposed uses; c) prepare, at the earliest possible time, a biological assessment to determine whether any threatened and endangered species may be affected by the proposed uses or the agency's changes from the conditional classification for those uses; d) engage in consultation with FWS regarding the potential adverse effects of clothianidin on threatened and endangered species and critical habitat; and e) ensure that the agency, registrants, and users of clothianidin products would not make any irreversible or irretrievable commitment of resources with respect to the sale and use of these compounds prior to EPA initiating and completing consultation with FWS. EPA's Section 7 failures occurred despite clear evidence in the agency's own risk assessment documents that EPA's actions would adversely affect particular listed species and posed a risk to broad suites of listed

species. These actions constitute a violation of the ESA within the meaning of 16 U.S.C. § 1540(g).

- 160. Scientific information on the impacts of clothianidin on invertebrates, birds, and ecosystems compels ESA § 7 effects determinations and consultation with FWS. Such information includes, but is by no means limited to, the March 2013 report by the American Bird Conservancy, which shows high direct and indirect mortality risks to a broad suite of birds from clothianidin products. EPA's continuing authority over the conditional and unconditional registrations of these insecticidal products constitutes ongoing action and it has violated its continuing obligation to follow the requirements of the ESA.
- 161. EPA further failed to comply with Section 7 of the ESA when it approved the label language for the clothianidin products listed in Appendix A; the products pose adverse effects to ESA-listed species because of this failure.
- 162. EPA's failures to comply with the ESA have allowed the clothianidin products to directly and indirectly harm and otherwise "take" federally-listed species, including, but not limited to, plant pollinators and birds, and have also adversely impacted critical habitats, damaging Plaintiffs' ability to enjoy and utilize those species and habitats and Plaintiffs' interests in their existence and well-being.

FOURTEENTH CLAIM

EPA's Actions in Approving Thiamethoxam Products and Labels Violated the ESA

- 163. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 162, as though fully alleged herein.
- Appendix B over the last thirteen-year period, EPA violated Section 7 of the ESA by failing to:
 a) ensure, in consultation with FWS, that the EPA-approved uses of thiamethoxam would not be likely to jeopardize the continued existence of any threatened or endangered species or result in the destruction or adverse modification of the critical habitat of such species; b) request from FWS information on whether any threatened or endangered species, or designated critical habitat, may be present within or near the areas of the proposed uses; c) prepare, at the earliest

1 possible time, a biological assessment to determine whether any threatened and endangered 2 3 4 5 6 7 8 9 10

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species may be affected by the proposed uses or the agency's changes from the conditional classification for those uses; d) engage in consultation with FWS regarding the potential adverse effects of thiamethoxam on threatened and endangered species and critical habitat; and e) ensure that the agency, registrants, and users of thiamethoxam products would not make any irreversible or irretrievable commitment of resources with respect to the sale and use of these compounds prior to EPA initiating and completing consultation with FWS. EPA's Section 7 failures occurred despite clear evidence in the agency's own risk assessment documents that EPA's actions would adversely affect particular listed species and posed a risk to broad suites of listed species. These actions constitute a violation of the ESA within the meaning of 16 U.S.C. § 1540(g).

- 165. Scientific information on the impacts of thiamethoxam on invertebrates, birds, and ecosystems compels ESA § 7 effects determinations and consultation with FWS. Such information includes, but is by no means limited to, the March 2013 report by the American Bird Conservancy, which shows high direct and indirect mortality risks to a broad suite of birds from thiamethoxam products. EPA's continuing authority over the conditional and unconditional registrations of these insecticidal products constitutes ongoing action and it has violated its continuing obligation to follow the requirements of the ESA.
- EPA further failed to comply with Section 7 of the ESA when it approved the 166. label language for the thiamethoxam products listed in Appendix B; the products pose adverse effects to ESA-listed species because of this failure.
- 167. EPA's failures to comply with the ESA have allowed the thiamethoxam products to directly and indirectly harm and otherwise "take" federally-listed species, including, but not limited to, plant pollinators and birds, and have also adversely impacted critical habitats, damaging Plaintiffs' ability to enjoy and utilize those species and habitats and Plaintiffs' interests in their existence and well-being.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

- 168. Direct EPA to fully consider the information Plaintiffs submitted and the effects on ESA-listed species on the question of "imminent hazard" of clothianidin use. The Court should order EPA to reconsider its final action of July 17, 2012, when Defendants denied an imminent hazard pursuant to the Plaintiffs' Petition to suspend clothianidin without considering the full information filed by Plaintiffs and without consulting with FWS under the ESA on whether a hazard was posed to threatened and endangered species and their critical habitats. The Court should direct EPA to consider all of the information filed related to imminent hazard, to consult with FWS under Section 7 of the ESA, and to issue a new decision on the question of imminent hazard.
- use approvals, for which a "notice of receipt of application" and/or a "notice of issuance" were not published in the Federal Register, are in violation of the FIFRA and its implementing regulations, and vacate them. The Court should issue a declaratory judgment that those approvals lacking public notices and an opportunity for public comments violated 7 U.S.C. § 136a(c)(4) and 40 C.F.R. § 152.102; and that those approvals should be vacated until and unless EPA provides such notices and opportunity.
- approvals violated the FIFRA and vacate them. The Court should issue a declaratory judgment that compliance with the conditions EPA placed on the pesticide registrations at issue has been unlawfully withheld and unreasonably delayed under the FIFRA and the APA, and should vacate them. Further, the Court should issue a declaratory judgment that EPA's removal of conditions and allowance of unconditional registrations for multiple thiamethoxam and clothianidin products violated the FIFRA's conditional use provisions, was arbitrary and capricious, and caused unreasonable adverse effects to the environment. The Court should vacate these unlawful registrations.

28 | 176. Grant such other relief as the Court deems just and proper.

- 171. Order EPA to immediately suspend the registrations of clothianidin and thiamethoxam. The Court should direct EPA to suspend all approved outdoor uses of clothianidin and thiamethoxam, and issue a stop sale, use or removal order for all such approved outdoor products, pending compliance with the many unsatisfied conditional registration requirements to provide outstanding safety data including, but not limited to, the preparation, publication, and agency review of a field study sufficient to support a finding that these compounds do not pose unreasonable adverse effects to honey bees and other insect pollinators.
- 172. <u>Direct EPA to cure clothianidin's and thiamethoxam's inadequate labels.</u> The Court should declare that clothianidin and thiamethoxam products are misbranded with labels and use directions that are inadequate to prevent unreasonable adverse effects to the environment, to beekeepers and honey producers, and to ESA-listed species. The Court should order EPA to develop new product labels and directions fully adequate to advise users on how to prevent these adverse effects.
- 173. <u>Direct EPA to comply with the ESA.</u> The Court should order EPA to comply with the ESA by making the required "effects" determinations, and initiating and completing consultation with FWS concerning clothianidin and thiamethoxam products' impacts on native endangered and threatened species and their critical habitats. The Court should order EPA to ensure that uses of these insecticides do not "take" threatened and endangered species or affect their critical habitats without appropriate mitigation and should enjoin any further use of the insecticides prior to completion of the ordered consultations.
- 174. Enjoin proposed new clothianidin and thiamethoxam product uses. The Court should enjoin EPA from approving any pending outdoor use approvals for clothianidin or thiamethoxam, or any other future proposed outdoor uses of them, until the agency complies with all of the Requests for Relief herein for the currently registered uses to avoid unreasonable adverse effects to Plaintiffs and on the environment.
- 175. <u>Award Plaintiffs the costs of this litigation</u>, including reasonable attorneys' fees and expert witness fees; and
- FIRST AMENDED COMPLAINT FOR DECLARATORY & INJUNCTIVE RELIEF

Respectfully submitted this 31st day of May, 2013. /s/ Sylvia Shih-Yau Wu SYLVIA SHIH-YAU WU (State Bar No. 273549) GEORGE A. KIMBRELL (Pro Hac Vice) PETER T. JENKINS (Pro Hac Vice) PAIGE M. TOMASELLI (State Bar No. 237737) Center for Food Safety 303 Sacramento Street, 2nd Floor San Francisco, CA 94111 T: (415) 826-2770 / F: (415) 826-0507 Emails: gkimbrell@centerforfoodsafety.org pjenkins@centerforfoodsafety.org ptomaselli@centerforfoodsafety.org swu@centerforfoodsafety.org Counsel for Plaintiffs